one or more continuing application(s). Applicants acknowledge the withdrawal of all of the rejection made in the previous Office Action mailed on June 7, 2000.

1. Rejections under 35 U.S.C. §112, second paragraph

Claims 36 and 38-40 are rejected as being indefinite. The Examiner alleges that claim 36 is vague because it fails to spell out the complete name of the term "HA-tag." Claim 36 has been amended to reflect that this term is an abbreviated nomenclature for "hemophilus influenza hemaglutinin." The Examiner suggested this language and the complete phrase is provided on page 93, lines 13-17 of the specification.

The Examiner alleges that claim 38 is not clear in the recitation of "naturally occurring" polypeptide. In an effort to expedite prosecution, claim 38 is has been canceled.

In view of the above clarifications and cancellation of claim 38, it is requested that this rejection be withdrawn.

2. Rejections under 35 U.S.C. §112, first paragraph

Claims 9, 23-26, 28, 35, 36 and 38-40 are rejected as containing subject matter that is not sufficiently described in the specification as filed. The Examiner alleges that claims 23-26, 28, 35 and 36 encompass a genus of polynucleotides which may vary significantly in structure from the nucleic acid molecule of SEQ ID NO:1 or any nucleic acid molecule that codes for the amino acid sequence of SEQ ID NO:2.

The Examiner alleges that because of the "open language, the claims are drawn to polynucleotides which may vary considerably from the disclosed polynucleotides of SEQ ID NO:1 and from the nucleotides consisting of a coding sequence for SEQ ID NO:2." The Examiner states that because the polynucleotides vary then the polypeptides will accordingly vary, and without a reasonable ability to predict the function of the encoded proteins, the skilled artisan cannot envision the many proteins encoded by the claimed polynucleotides. The Examiner concludes that adequate written description of a genus of nucleic acid molecules requires more than a mere statement that the encompassed species are part of the invention.

Applicants traverse this rejection. "The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed..." USPTO Guidelines for Examination of Patent Applications under Section 112, Fed. Reg. 66(4):1099-1111. The Examiner has not explained the alleged written description deficiencies in sufficient detail. Moreover, Applicants respectfully note that the Examiner appears to be basing the present rejection on legal requirements relating to the enablement requirement – *e.g.*, "conception of the claimed polynucleotide molecules is not achieved until reduction to practice has occurred, regardless of the complexity of simplicity of the method of isolation of the claimed polynucleotides.. . ." Office Action Page 6.

In the present case, the examiner has not met her burden of presenting the evidence required to establish a rejection for lack of written description. The written description requirement ensures that the skilled artisan would understand, based on the specification, that the inventor possessed the claimed invention at the time the application was filed. *Vas-Cath v. Marhurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991). Literal correspondence between the claims and the specification is not required. *See In re Wertheim*, 541 F.2d 257, 265 (CCPA 1976). Furthermore, breadth alone is not sufficient basis for rejecting claims under the written description requirement. The Examiner is required to set forth, with specificity, the reasons for the rejection. See Fed. Reg. 66(4):1106-1107 (2001).

The claims set forth, with structural detail, recitation of specific sequence and specific domains that may be present or absent in the claimed molecules. See, for example, pages 51 and 52 of the specification. Having set forth the specific amino acid sequences of these fragments in SEQ ID NO:2, nothing more is needed to describe these sequences, so that one of skill in the art would know that the present Applicants had invented these fragments. Identification of these fragments is provided by the sequences supplied.

Furthermore, the fact that the claims recite nucleic acid molecules "comprising" one or more of the recited species is not, *per se*, relevant to the issue

of written description. "Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Fed. Reg. 66(4):1106 (2001). Applicants note that the Examiner appears to object to the fact that the claims encompass numerous nucleic acid molecules that encode the full length amino acid sequence set forth in the recited SEQ ID NO:2 and specified fragments thereof. However, the claims set forth, with specificity, the invention claimed in the present application – the nucleic acid molecules that encode the amino acid sequence of SEQ ID NO:2 with specific recited domains deleted. In view of these arguments, it is requested that this rejection be withdrawn in regard to claims 9, 23-26, 35 and 36.

Further, the Examiner alleges that claims 38-40 are drawn to nucleic acid molecules that encode polypeptides and which hybridize to the nucleic acid molecule as defined in claim 2. The Examiner interprets claims 38-40 as drawn to "...a genus of polynucleotides of varying size and encoding polypeptides of any biological function." The rejection as directed to claims 38-40 is moot in view of their cancellation.

3. Rejection under 35 U.S.C. 101

Claims 2-5, 9 and 23-40 are rejected because the Examiner alleges that the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility. The Examiner states that the utility of an invention must be supported by an assertion of utility in the specification that is readily apparent to one of skill in the art. The Examiner acknowledges that the claimed nucleic acids appear to encode a novel protein which belongs to the ALK family, but then alleges that the utility of the nucleic acid encoding SEQ ID NO:2 has not been established in the art.

Applicants traverse this rejection. The instant specification provides information describing substantial and specific utility for the present invention. The sequence of the serine-threonine receptor kinase, identified as ALK-7 in the specification, is extensively characterized, and its expression patterns have been analyzed. See pages 87-92. The specification states that ALK-7 is expressed in many different types of cells. See pages 89-92. Further, the human ALK-7 of the

present invention is expressed in more restricted areas of the brain, i.e., hippocampus, hypothalmic nuclei, sustantia nigra and pituitary gland. This restricted expression pattern strongly suggests a role for human ALK-7 in the growth and/or survival of neurons and its relevance in treatment of diseases, such as Parkinson's disease, Huntington's disease and Alzheimer's disease. See, for example, page 31 of the specification.

Further as noted in the paragraph bridging pages 17 and 18, the biological activity of ALK-7 is related to cell activities that include cell proliferation, metastasis, tumor escape, cell adhesion, transformation and apoptosis. In this regard, the specification discusses that inhibitors or modulators of ALK-7 can have therapeutic value in the treatment of proliferative diseases such as cancer. See pages 31-32.

The use of the ALK-7 receptor to identify therapeutic agents for treatment of cancer is a specific utility that is described in the specification. *In re Brana* 51 F.3d 1560 (Fed. Cir. 1995) (finding specific utility). The specification also states that ALK-7 is useful for identification of agents for treatment of neurological diseases and conditions. These uses constitute a substantial "real world" utility within the meaning of §101. As stated by the Federal Circuit, an invention lacks utility only if it is "totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.* 977 F.2d 1555, 1571 (Fed. Cir. 1992). The examiner has failed to demonstrate that the claimed proteins are incapable of achieving such a result.

Functions of ALK-7 were deduced, based on the structural and functional characteristics of the ALK-7 receptor and the expression patterns of ALK-7, all of which are described in the specification. Structural similarity of inventive compounds, compared with other compounds sharing similar structural characteristics has been accepted as evidence of utility. *In re Brana* 51 F.3d 1560 (Fed. Cir. 1995). In the present case, the presence of catalytic and other domains, combined with expression data, establishes utility. It is requested that this rejection be withdrawn.

CONCLUSION

Reconsideration of the rejections is requested. Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, a telephone call to the undersigned, at the telephone number listed below, is courteously invited.

Respectfully submitted,

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Marked-up version of claims

36. (**TWICE AMENDED**) The nucleic acid molecule of Claim 35, wherein said truncated polypeptide is obtained by insertion of a hemophilus influenza hemaglutinin-tag (HA-tag) [an HA-tag] at position 230 of the amino acid sequence set forth in SEQ ID NO:2.